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09/889,085	01/09/2002	Patricia Lynne Conway	28053/38258	6842

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 04/22/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/889,085

Applicant(s)
Conway et al.

Examiner
Vera Afremova

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1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 3, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above, claim(s) 20-40 and 63-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 41-62, and 76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 6) ☐ Other: _____

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DETAILED ACTION

Applicants' election without traverse of the Group I invention (claims 1-19, 41-62 and 76) in Paper No. 14 filed 3/03/2003 is acknowledged. Claims 20-40 and 63-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Claims 1-19, 41-62 and 76 are under examination in the instant office action.

Claim Objections

Claims 18 and 19 are objected to because of the following informalities: the Latin names of microorganisms should be italicized. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-19, 41-62 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and claims 41, 42 and 76 are indefinite with respect to components of the claimed compositions because differences between recited "microbial preparation" and "product" are uncertain as claimed. A microbial preparation is also a product. Thus, claims 41, 42 and 76 fail to further limit the claimed invention. For example: claim 41 requires incorporation of microbial preparation "in a product" of claim 20 which is the same as product of claim 1. Furthermore, claims 42 and 76 again require incorporation of microbial preparations into some unidentified products. Thus, the vague and broad terminology such as "a product" or "the

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product” in the instant claims fails to point what are the intended components of the compositions of claims 1, 41, 42 and 76 or how many subsets of “microbial preparations” are within the compositions of the claims 41, 42 and 76.

In the instant office action claims 1, 2, 4-19 and 41 are interpreted as being drawn to microbial preparations alone and/or without starch, food, feed, pharmaceuticals. Claims 3, 42-62 and 76 are interpreted as drawn to incorporation of microbial preparations into other compositions or products including starch, food, feed, pharmaceuticals, etc.

Claim 15 is rendered indefinite by the phrase “in use” since the claim does not set forth any characteristics of the claimed preparations in applications as intended. Further, this claim contains several terms of relative degree, for example: “elevated temperatures, low temperatures”, “low pH, high pH”, etc. which render the claim indefinite. These terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claim 15 does not appear to have any actual meaning since “aeration” and/or “freeze-drying”, for example, are regular conditions suitable for a majority of microbes and, thus, the claimed conditions or applications can not be considered as “stresses”.

Claim 18 is indefinite and has improper Markush group because it is uncertain whether the end of the Markush group due to some confusing punctuation. It is suggested to write, for example: “selected from the group consisting of A, B, C and D”. MPEP 2173.05 (h). In alternative, it is uncertain whether “leuconostoc” and “yeasts” are required to be present in the

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whole “microbial preparation” or not. It is also noted that yeasts do not belong to the group of “lactic acid bacteria”. Thus, the meaning of the claim is indefinite.

Claim 19 is indefinite and has improper Markush group because the differences between the claimed members of the Markush group can not be delineated. This claim combines common microbial names with the Latin names wherein their meaning is overlapping. For example: “bifidobacteria” and “acidophilus” are both lactic acid bacteria. Moreover “*acidophilus*” is a species name of *Lactobacillus acidophilus*. The differences between the claimed “pseudomonads” and the claimed “Alcaligenes” are uncertain since both are pseudomonads and/or belong to the genus of *Pseudomonas*. It is suggested to use the Latin names of microorganisms which are intended.

Claim 62 is indefinite and fails to point out how starch is “used” in a product comprising starch and microbial preparation wherein the microbial preparation are harvested from the starch-containing medium. Is the range 1-10% intended for the microbial growth medium “used” for culturing and obtaining “harvested” microbes? Is the amount of 1-10% starch added to the microbial preparations comprising “harvested” microbes?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-19, 41-51, 61-62 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,143,845 [A].

Claims are directed to a microbial preparation comprising harvested microbes with improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of resistant starch into microbial preparations and/or into products with microbial preparations, to the use of resistant starch RS2 or RS3 and to the use of starch derived from potatoes in the microbial preparations and/or in the products with microbial preparations. Some claims are further drawn to microbial preparations being characterized by stress resistance, to the use of various microorganisms including lactic acid bacteria in microbial preparations. Some claims are further drawn to incorporation of microbial preparations into various food, feed, pharmaceutical and biocontrol products suitable for delivery of microbial preparations. Some claims are further drawn to the amounts of resistant starch in the product and/or in the microbial preparations such as 0.1-90 % (w/) or 1-10% (w/w).

US 5,143,845 [A] discloses a microbial preparation comprising harvested microbes having improved characteristics or a microbial preparation with activated bacteria (see abstract). The microbial preparation is incorporated into a pharmaceutical product comprising potato starch (col. 2, lines 45-46 or col. 3, lines 16-25) and/or into other food or feed products suitable for delivery of probiotic microorganisms (col. 1, line 39-40). The harvested bacteria were grown and/or activated on a basal medium with potato starch (example 2). The cited patent teaches that

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the activated microbial preparations are capable to effectively proliferate (col. 4, lines 18), that they promote recovery of intestinal flora (col. 3, lines 65-68) and that they are characterized by heat stability, dry stability and drug stability (col. 2, lines 53-55). Thus, the activated microbial preparation of the cited patent are characterized by an "increased" "survival/recovery rate" and they are substantially unaffected by stresses within the meaning of the claims 1 and 15. The bacteria include representatives of lactic acid bacteria, *Bacillus* and others (col. 2, lines 34-44) as the microbial preparations of claims 16-19.

The potato starch of the cited patent is considered to be identical to the "resistant starch" including "RS2" and/or "RS3" of the claimed invention in the light of claim 5, which is drawn to the use of potato starch, and in the light of the applicants' definitions (see specification page 7, par. 2) which refers to the IDS reference by Brown et al. [IDS-6] wherein "RS2" and/or "RS3" are disclosed as cooked and cooled starchy foods and/or raw potato starch (see table 1). Thus, the potato starch in the microbial composition and in the product with microbial compositions of the cited patent is identical to the resistant starch in the claimed microbial preparation and the claimed product with microbial preparations.

The cited patent discloses that the product with microbial preparation comprises about 50% (w/w) of starch (col. 3, line 24) or that the microbial preparation comprise 10% of starch (col. 5, line 53) what is within the meaning of claims 61 and 62 and within the claimed ranges.

Thus, the cited patent US 5,143,845 [A] anticipates the claimed invention.

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Claims 1-19, 41-62 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,050 [B] in the light of evidence by US 5,714,600 [C].

Claims are directed to a microbial preparation comprising harvested microbes with improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of resistant starch into microbial preparations and/or into products with microbial preparations, to the use of resistant starch RS1, RS2, RS3 or RS4, to the use of resistant starch derived from maize, rice, barley, potatoes and to the use of resistant starch having amylose content at least 40%, 70 %, 80% or 90% in the microbial preparations and/or in the products with microbial preparations and to the use of resistant starch which is chemically or physically treated including chemical modification by esterification, acidification, etc.. Some claims are further drawn to microbial preparations being characterized by stress resistance, to the use of various microorganisms including lactic acid bacteria in microbial preparations. Some claims are further drawn to incorporation of microbial preparations into various food, feed, pharmaceutical and biocontrol products suitable for delivery of microbial preparations. Some claims are further drawn to the amounts of resistant starch in the product and/or in the microbial preparations such as 0.1-90 % (w/) or 1-10% (w/w).

US 6,060,050 [B] teaches a microbial preparation comprising harvested microbes with improved characteristics associated with survival/recovery in intestinal tract and it teaches incorporation of resistant starch into microbial preparations and/or into products with microbial preparations (col. 1, lines 55-65). The cited patent teaches the use of resistant starch RS1, RS2,

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RS3 or RS4 (col. 1, line 54) which is derived from maize, rice, barley, potatoes (col.4, lines 3-5) and to the use of maize resistant starch which is characterized by amylose content of more than 50% or more than 80% (col. 3, lines 62-65). The cited US 6,060,050 refers to the use of maize resistant starch as disclosed in WO94/03049, which is now US 5,714,600, wherein the maize resistant starch having more than 80% of amylose include amylose contents of "at least 90% " (see US 5,714,600 col.2, line 67). The resistant starch in the compositions of US 6,060,050 chemically or physically treated including chemical modification such as esterification, acidification, etc. (col. 4, lines 15-21). The microbial preparations in the compositions of US 6,060,050 have been cultured or grown on resistant starch containing media (col. 5, lines 31-36; col. 9, lines 50-55 and table 4) in order to select probiotic microorganisms able to utilize resistant starch (col. 2, lines 14-17) and to survive in the intestinal tract (col. 1, line 63-64). The microbial preparations in the compositions of US 6,060,050 have a stress resistance including resistance to freezing and to freeze-drying (col. 2, line 50). The cited patent discloses to the use of various microorganisms including lactic acid bacteria in microbial preparations (col. 2, lines 20-25) and incorporation of microbial preparations into various food, feed, pharmaceutical and biocontrol products suitable for delivery of microbial preparations (col. 4, lines 55-60). The cited patent discloses amounts of resistant starch in the product and/or in the microbial preparations such as 2-20 % w/w (col. 2, lines 57-58, col.7, lines 50-65 and col.8, lines 15-25).

Thus, the cited patent US 6,060,050 anticipates the claimed invention.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19, 41-62 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,143,845 [A] and US 6,060,050 [B] taken with Brown et al. [IDS-6] and US 5,714,600 [C].

Claims as explained above.

Both US 5,143,845 [A] and US 6,060,050 [B] are relied upon for the disclosure of microbial preparations and products with microbial preparations containing resistant starch. The cited US 5,143,845 [A] discloses the use of potato derived resistant starch in the microbial preparations/products but it is lacking particular disclosure related to the use of chemically modified maize resistant starch having high amylose contents of at least 40-90% . But the cited US 6,060,050 [B] teaches microbial preparations/products with chemically modified maize resistant starch having high amylose contents of at least 40-90% as explained above.

Further, the reference by Brown et al. [IDS-6] is relied upon for the teaching directed to beneficial properties of resistant starch in the microbial preparations/products (table 2) including improved robustness of probiotic cultures, improved viability of probiotic cultures in food compositions. It is also teaches that the high amylose maize resistant starch is particularly

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beneficial in compositions with lactic acid bacteria because it enhance bacterial survival and stress resistance (page 607, col. 1).

The cited patent US 5,714,600 [C] is relied upon to demonstrate that physically and/or chemically modified resistant starch (col.7, lines 13-15) including maize starch having high amylose contents of at least 40-90% (col.2, lines 63-67) are available in the prior art and they have been suggested for various compositions including foods and other industrial products (col. 1, line 24) .

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify compositions of US 5,143,845 [A] by incorporation of maize resistant starch of US 6,060,050 [B] or of US 5,714,600 as taught for the compositions of US 6,060,050 [B] with a reasonable expectation of success in increasing survival and recovery of microbial preparations in various products as suggested by Brown et al. [IDS-6]. One of skill in the art would have been motivated to use high amylose maize resistant starch in microbial preparations/products for the expected benefits related to the improved viability and to stress resistance of probiotic cultures {Brown et al. [IDS-6]}. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19, 41-62 and 76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,221,350 [D].

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to microbial or probiotic preparations and

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compositions comprising microorganisms and resistant starch. Claims of US 6,221,350 appear to be narrower and they require microorganisms, resistant starch and oligosaccharide in the composition. Some of the claims of the instant application appear to be broader and they are not required to contain resistant starch, for example: claim 1. However, some of the claims of the instant applications are drawn to compositions comprising both microorganisms and resistant starch, for example: claim 3 or 49. The microorganisms in the compositions of the instant application and of the cited patent are identical, for example: see patented claims 3-6 and see pending claims 17-19. The resistant starch in the compositions of the instant application and of the cited patent is identical, for example: see patented claims 9-12 and pending claims 50-60. Although the claims of the instant application are not clearly directed to the use of oligosaccharide, they encompass the use of modified starches wherein the enzymatically modified starches, for example, are reasonably expected to comprises at least some amounts of oligosaccharide which are components of starches.

Accordingly, the claimed compositions are obvious variants. Thus, the inventions as claimed are co-extensive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on Monday to Friday from 9:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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April 18, 2003

VERA AFREMOVA

PATENT EXAMINER

A handwritten signature in black ink, appearing to read 'V. Afremova', followed by a long horizontal line.